



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,158	02/09/1999	ZHENG YU YUAN	342312000600	8469

1095 7590 12/04/2002

THOMAS HOXIE
NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT
564 MORRIS AVENUE
SUMMIT, NJ 079011027

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/04/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/248,158

Applicant(s)

Yuan et al

Examiner
Maurie G. Baker, Ph.D.

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Sep 9, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 3, 5-10, and 19 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 3, 5-10, and 19 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other: _____

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to **Art Unit 1639**.

1. The Response filed on September 9, 2002 (Paper No. 28) is acknowledged. Claims 1, 8 and 10 were amended in this response and claims 21-28 were cancelled. Therefore, claims 1, 3, 5-10 and 19 remain pending and under examination.

Withdrawn Rejections

2. The previous rejections under 35 U.S.C. 112 and 102 are withdrawn in view of applicant's amendments and arguments. A new rejection is set forth below. Since the new rejection was not entirely necessitated by amendment to the claims, the case remains in non-final status.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent

any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 5-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasila et al (US 5,972,595; of record) in view of Brown et al (High Throughput Screening, 1997).

Kasila et al teach a method for measuring enzyme activity using a solid support coated with a hydrophobic layer (see column 2, lines 10-23). Specifically, the solid supports are 96-well FlashplatesTM (which are a scintillating material; see definition, column 2, lines 48-50) coated with an artificial lipid layer in various ways (see, for example, column 4, lines 25-38 and column 5, line 63 through column 6, line 22). Enzyme substrates are bound via hydrophobic interactions within the lipid layer (column 3, lines 26-39). The biochemical transformation of the bound substrate causes a cleavage of a portion of the molecule, thus rendering it hydrophilic (see patented claims, especially claim 1). The hydrophilic portion is washed away, thus reducing the level of scintillation (see, for example, column 5, lines 36-60). The assay of Kasila et al can be used to study various enzymes and is designed to study them in high-throughput fashion (column 6, lines 24-60).

Kasila et al lacks the specific teaching of where the “reaction product of the chemical or biochemical transformation binds to the scintillating material” to produce

a signal above background. The reference teaches the opposite scenario (reaction product is washed away, thus reducing the level of scintillation); however, the reference teaches that a variety of enzyme assays can be conducted using their methodology with different method steps, enzymes, labels and solid supports (see column 3, line 25 – column 4, line 19). For example, Kasila et al teach that the “enzyme activity can be measured by detecting the reporter label fragments in the aqueous material” (column 4, lines 8-9). Importantly, Kasila et al teach “the use of a substrate that allows the study of enzyme activity in samples without the need to extract the reaction products” and that “[w]ith appropriate substrate design” their invention “can be used to study a variety of enzymes...for which the assay methods otherwise require extraction steps” (column 3, lines 10-25). Thus, it is the examiner’s position that Kasila et al teach the general conditions of the instant claims and to modify the teachings of the reference where the “reaction product of the chemical or biochemical transformation binds to the scintillating material” to produce a signal above background would be obvious to one of ordinary skill. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Moreover, the binding of radioactive elements to scintillating material in an enzyme assay was well established in the art at the time of filing. For example, Brown et al teach the advantages of using the microplate surface scintillation effect in general (page 317), and for enzyme assays in particular (Section IV, beginning on

page 321). These offer the opportunity to save time and cut costs (see Section VI, Summary, page 327).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the method of Kasila et al where the “reaction product of the chemical or biochemical transformation binds to the scintillating material” to produce a signal above background. The motivation is two-fold: (1) because the general conditions of a claim are disclosed in Kasila, it is not inventive to discover the optimum or workable ranges by routine experimentation (*In re Aller*, cited above); also (2) since the binding of radioactive elements to scintillating material in an enzyme assay was well established in the art at the time of filing (as evidenced by Brown et al), it would have been obvious to one of ordinary skill that this format was a desirable one for enzyme assays. Brown teaches that such assays save time and cut costs (see above). Also, Kasila et al teach that “[w]ith appropriate substrate design” their invention “can be used to study a variety of enzymes...for which the assay methods otherwise require extraction steps” and that the “particular substrate to use is designed or selected for its susceptibility to the action of the enzyme and an appropriate location for the label” (column 3, lines 10-25).

Status of Claims/Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
November 26, 2002

A handwritten signature in black ink, appearing to be 'MB' followed by a horizontal line.

MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER